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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,799	08/29/2003	Barry Eisenstein	50150/005003	2013

21559 7590 03/26/2007

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/652,799	EISENSTEIN, BARRY	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10, 12, 35-44, 46-48 and 51-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,35-44,46-48 and 51-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment, request for reconsideration and remarks, all filed 12/22/06. Examiner further acknowledges the receipt of IDS filed 01/13/05. Claims 1-10, 12, 35-44, 46-48 and 51-53 are pending.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10, 12, 35-44, 46-48 and 51-53 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The specification as originally filed does not support the scope of the presently claimed composition of the claims, that is, a method where the administration method is solely oral. Other methods are clearly contemplated by the as filed specification. For example, the specification at paragraphs [0008], [0011], and Example 1 supports oral, rectal, intravenous and subcutaneous administration.

Applicant may overcome this rejection by amending the claims to be commensurate with the administration methods disclosed in the specification (paragraph [0008]), where oral, rectal and subcutaneous and intravenous administrations are envisioned.

Response to Arguments

3. Applicant's arguments filed 12/22/06 have been fully considered but they are not persuasive.

Applicant argues that the specification meets the written description requirement for the administration of rifalazil alone or in combination with one or more antibiotics as shown in paragraphs [0023] and [0026]; that oral administration (gavage) for rifalazil alone has been evaluated by Anton P. M. et al.; abstract ID No. 102471, Publishing ID No. T1741, presented at the American Gastroenterological Association Meeting, May 17-22, 2003; Anton P.M. et al., Gatroenterology 124:A558,2003.

Response:

Examiner recognizes that the as filed specification envisions the administration of rifalaxil alone or in combination with antibiotics as in Example 1. However, the method is not restricted to oral administration alone as the claim suggests in reciting "said method consisting of orally ...." Rifalaxil is envisioned for oral, rectal, subcutaneous (last 2-lines of paragraph [0008] administration.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-10, 25-44 and 48 remain rejected under 35 U.S.C. 102(e) as being anticipated by Michaelis et al. (US 2004/0034021).

Michaelis discloses method of treating infection of clostridium difficile by administering composition that comprises rifalazil; the composition that is administered may further contain one or more antibiotics (paragraphs [0013], [0014], [0054], [0114], [0115], [0124], [0145], and claims 1-62). Michaelis does not exclude oral administration except that Michaelis preferred using parenteral administration when treating many nosocomial and serious community acquired infections (paragraph [0083]). This paragraph does not point to exclusionary use of parenteral administration.

Response to Arguments

6. Applicant's arguments filed 12/22/06 have been fully considered but they are not persuasive.

Applicant argues that Michaelis is concerned specifically with intravenous administration; that Michaelis prefers intravenous administration for lack of predictability in bioavailability of orally administered rifalazil; and that when Michaelis orally administers rifalazil, it is done concomitantly with, or subsequent to , the initial intravenous administration.

Response:

While Michaelis prefers intravenous administration, Michaelis does not rule out oral administration. For example, rifalazil is orally administered in Example 5 without concomitant or preceding intravenous administration. Therefore, the rejection of the claims over Michaelis is maintained.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER